THE ROLE OF PERIOPERATIVE CRITICAL CARE SUPPORT IN A REGIONAL HOSPITAL:

A prospective survey at New Somerset Hospital

A research report presented to the faculty of Health Sciences at the University of Cape Town in partial fulfilment of the requirements for the degree of Master of Medicine in Anaesthesia

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Statement of Declaration

I, Kathleen Georgia Delport, hereby declare that the work on which this dissertation is based is my original work and that all sources have been accurately reported and acknowledged and that neither the whole work nor any part of it has been, is being, or is to be submitted for any other degree in this or any other university.

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Date: 18 February 2018

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ABSTRACT

THE ROLE OF PERIOPERATIVE CRITICAL CARE SUPPORT IN A REGIONAL HOSPITAL: A prospective survey at New Somerset Hospital

Background:
Postoperative critical care support is required for emergency and elective cases having either major surgery, with poor physiological states or significant comorbidities, and for support following unexpected surgical or anaesthetic complications. Research suggests that as many as 48% of all critical care unit (CCU) admissions occur postoperatively, yet limited literature is available regarding the support role that on-site critical care availability provides for surgery. Research into this area is therefore necessary to understand the impact of accessible critical care support, especially in hospitals at regional and district level.

Objectives:
The objective of this research is to contribute to the literature on perioperative critical care by presenting data quantifying and describing the patients requiring postoperative critical care at New Somerset Hospital (NSH) – a regional hospital in Cape Town, in the Western Province of South Africa. Further to this, the research aims to identify cases that would not have proceeded here if the option of on-site postoperative critical care did not exist.

Methods:
Data was collected using a prospective survey spanning a six-month period from June 2015 to November 2015. The data represented two sets of patients:
1) every case done, documenting whether they would have proceeded at NSH without the presence of a critical care unit;
2) each admission to a critical care service directly from theatre, describing their indications for admission and their postoperative critical care pathway, interventions and outcomes.

Results:
A total of 3247 complete cases were included in the analysis. Of the total sample of cases assessed, 66 (2%) were supported by critical care at NSH, of which roughly half (31 cases) would not have proceeded at NSH without availability of a critical care bed. Of these patients, 7 did not have a bed reserved preoperatively, and were not admitted, highlighting an important subgroup of patients: those not admitted to a CCU, but yet received surgery at NSH solely due to the potential of postoperative critical care support there. New admissions amounted to 48 (1.5%) of all cases of which 43 were emergencies, and 14 were unplanned. 45% of admissions required monitoring or epidural care only, for which High Care would have been sufficient, while 55% received cardiorespiratory support.

Conclusion:
These results confirm that at NSH, an on-site CCU allows for cases to proceed that would otherwise have been transferred elsewhere. Of note, obstetrics accounted for 3 of the unplanned admissions, confirming that a level 2 obstetric service requires critical care support despite treating otherwise low risk patients. This data indicates that critical care plays a beneficial role in supporting a regional theatre service.

Further research is required in this field to determine whether these results can be generalised to other regional hospitals. This survey should help as baseline data, especially for studies to better assess quality and outcomes against national and international metrics.

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LIST OF ABBREVIATIONS

CCU	Critical Care Unit
ICU	Intensive Care Unit
HCU	High Care Unit
HDU	High Dependency Unit
NSH	New Somerset Hospital
UK	United Kingdom
SA	South Africa
SASA	South African Society of Anaesthetists
USA	United States of America
DoH	Department of Health
APACHE	Acute Physiology and Chronic Health Evaluation
ASA	American Society of Anaesthetists
ECMO	Extracorporeal Membrane Oxygenation

CHAPTER 1: LITERATURE REVIEW

1. Introduction

Since the establishment of the first Intensive Care Units (ICU) in the 1950s, the demand for critical care support has grown exponentially[1], with the number of patients often far exceeding the supply of available beds. This is especially true in developing countries where resources are relatively limited.[2]

There is evidence to suggest the requirement for perioperative critical care. For example, a study done in Nigeria in 2007 suggested that approximately 48% of intensive care admissions were for postoperative patients.[3] However, a review of the literature reveals a distinct lack of global publications in the field. Although scattered studies were found regarding postoperative admissions to a Critical Care Unit (CCU) from other developing countries such as India, Nigeria and Brunei,[4-7] none focused specifically on the perioperative support for surgical services at regional hospital level. Sometimes this support may simply be in the form of an available critical care bed allowing a facility to proceed in offering higher risk patients surgery. No literature was found where these surgical opportunities are assessed or documented.

The South African National Health Act of 2003[8], last published in 2012, states that a regional hospital should have between 200 and 800 beds. Its services extend to a defined regional drainage population and are limited to provincial boundaries. It receives referrals from several district hospitals, while having access to outreach and support from tertiary hospitals. It provides health services in the fields of trauma and emergency care, internal medicine, paediatrics, obstetrics and gynaecology, and general surgery on a 24-hour basis, and at least one of the specialties of orthopaedic surgery, psychiatry, anaesthetics and radiology. It also offers short term ventilation in a critical care unit.

Although the critical care unit may be available for postoperative care, literature from the United Kingdom (UK) and Ireland suggests that the presence of a High Care (HCU), or High Dependency Unit (HDU) is a potentially more cost-effective option to improve access to critical care support for patients requiring intermediate monitoring postoperatively.[9] There is no published data on such a facility at a regional hospital.

In order to better understand the role of Critical Care in the context of the research presented, the following concepts are explored below:

- Definitions of Critical Care and how they vary
- Relative availability of Critical Care Support in South Africa vs. Internationally
- Understanding the costs of Critical care
- Predictive factors for patients requiring critical care support
- Debating the regionalisation of critical care service models
- HDU's: an alternative postoperative care solution for some

2.1 Definitions of Critical Care Vary across the Globe

Critical or intensive care is a multidisciplinary and inter-professional specialty dedicated to the comprehensive management and support of patients having, or at risk of developing, acute, life-threatening organ dysfunction.[10]

Critical care units can be classified as general or specialised e.g. Obstetric, Cardiac. They also have either an "open" or "closed" arrangement. "Open" means the admitting physician or surgeon keeps the formal responsibility for the patient's care and treatment. A "closed" format means the patient is admitted to the unit and the responsibility for their treatment is transferred to the dedicated intensive care team.[11]

The definition of what constitutes the various divisions or levels of critical care is not internationally standardised, and may vary even within a single health care system. It is heavily shaped by public health priorities and regulatory requirements, as well as by economic factors, including resource and staff availability.[10]

According to the most recently updated South African Society of Anaesthetists (SASA) Practice Guidelines[12], three categories of CCU's are recognised in South Africa (SA):

1) **Category 3** refers to a tertiary intensive care facility that has the potential to offer the highest degree of patient care. The type of patient who is admitted to this unit may include, but is not limited to: those with multiple organ failure; requiring multidisciplinary intervention; requiring ventilation and haemodialysis, with second organ failure. Haemodynamically unstable patients, e.g. unstable myocardial infarction and immediate post-bypass surgery are also included here.

2) **Category 2** refers to a specialised organ support unit and here admitted patients require slightly less care than in category 3 and may include, but are not limited to, those who: require active system support such as intermittent positive-pressure ventilation (IPPV); have single-organ failure; airway problems; or conditions that require potent drug infusions e.g. inotropic medication.

3) **Category 1** refers to a high care or HDU where patients require intensive monitoring only, and include those who have: fluid, electrolyte or metabolic disturbances, e.g. diabetic pre-coma and postoperative monitoring; drug overdose that does not require IPPV; neuromuscular weakness not requiring IPPV; and single-organ dysfunction that does not require active support.

2.2 Relative Availability of Critical Care in SA vs. Internationally

Obtaining exact data to compare the number and utilisation of critical care beds between countries is not simple, as stated by Adhikari et al[2] in their review of the challenges and availability of critical care globally. The 1186 public sector beds in South Africa counted in 2008 by Naidoo et al[13] translates to a ratio of beds per capita of roughly 1:40000. However, if both the public and private sector units are included, the ratio is approximately 1:11000. The study does not differentiate between tertiary and regional facilities. Internationally this ratio varies widely from 1:4000 in the United States of America (USA), 1:17000 in UK to 1:62000 in Sri Lanka for example.[14] The reason for the scarcity of these units is multifold, with the major factors being expense and the availability of appropriately trained staff, as mentioned in a review by Tisherman *et al*. [15]

2.3 Critical Care Units are Costly, but Assessment of Expense is Not Simple

It is difficult to accurately assess the exact cost per patient in a CCU. Seidel *et al*[16] suggests that this is partly due to the variation in resource utilisation from patient to patient, influenced by factors such as case mix, illness severity, length of stay and variations in clinical practice. Different CCU's also have variable access to treatment methods e.g. Dialysis, ECMO (Extracorporeal Membrane Oxygenation) which subsequently influences the cost to a hospital of the unit. However, in addition to base costs such as staffing and equipment, Seidel *et al* recommend that estimating and calculating the average cost per patient is the most effective method of analysing cost to a facility.[16]

On-site critical care facilities also influence the running costs of a hospital in complex ways. Taking patients from a ward to intensive care increases availability of ward beds, but intensive care survivors can increase hospital costs owing to their potentially prolonged admission. There are also the increased costs to, and strain on, national health services to consider. A decrease in mortality of critically ill patients due to improved access and care to critical care support results in an increase in CCU survivors, who frequently have residual post-intensive care health problems requiring further long-term treatment and rehabilitation, as well as limited earning potential[17].

Keeping this in mind, CCU's do have a definite role in the health care system. The increasing need and motivation for available beds has prompted an increase in research related to the utilisation and validity of both medical and surgical CCU's.[2]

2.4 Which Patients Require Perioperative Critical Care Support

For most patients, risks of surgery are low and yet recent research confirms that complications postoperatively are an important cause of death, according to the multi-national African Surgical Outcomes Study (ASOS) published in 2018 by Biccard *et al.*[18] Despite the majority of patients presenting for surgery being low risk, postoperative complications occur in 18% of all cases, of which 16% are admitted to critical care with a mortality rate of 9.5%.[18] The complication rate post caesarean section is even higher, at 26%, but the critical care admission rate was not documented. In the UK, 10% of patients are at high risk of complications, and account for 80% of postoperative deaths.[19] A large cohort study done in Europe by Pearse *et al*[20] showed a higher than anticipated mortality rate in non-cardiac postoperative patients. ASOS also found that 95% of deaths occurred in the postoperative period. It is clear that more attention is required to understand how surveillance for physiological deterioration and postoperative care pathways can be improved.

The South African Surgical Outcomes Study (SASOS) published in 2015 by Biccard *et al*[21] noted that in South Africa, excluding neuro- and cardiac surgery and obstetrics, the rate of postoperative critical care admission in adults is 6.5%. 43.5% of these were unplanned, with a higher associated mortality rate. Most surgical cases requiring admission are for non-elective procedures. In Europe, where the number of available beds is generally increased, 7.7% of patients were admitted postoperatively, 60% for elective cases, and only 28.6% admissions unplanned.[20] These studies also share the view that the rate of postoperative deaths in patients not admitted to a CCU is higher than when patients are admitted, with death rates of 50% and 73% in South Africa and Europe respectively. These suggested low rates of admission to critical

care for patients at high risk of complications undergoing non-cardiac surgery are concerning.[20]

According to two studies done in India by Bhat et al[4] and Manjula et al[5], factors which serve as significant predictors of critical care admissions are males, age more than 60 years, ASA Grading III or IV, abdominal explorations, emergency operations, history of intraoperative arrhythmias/persistent tachycardia, major blood loss, hypotension requiring inotropic support, and oxygen saturation less than 90% on room air.[4 ,5] Interestingly, in a small study done in Ireland by Dawson *et al*[22] in 2012, it was shown that although elective orthopaedic cases appear to have a lower admission rate, with 1.8% of patients require perioperative critical care support, predictive factors are similar and include age, raised BMI, ASA2/3 and arthroplasty procedures.

However, not all surgery is performed at tertiary centres with an on-site critical care unit available. Various alternative options to increase access to improved perioperative care for patients of a certain acuity or risk profile are being assessed, such as the regionalisation of critical care and the establishment of HDU's in the UK and Ireland.[9]

2.5 Regionalisation of Critical Care and Associated "Hub and Spoke" Service Models

One could surmise that every hospital of reasonable size, offering a surgical service, should have the availability of a CCU. However, due to the factors mentioned including expense and a shortage of adequately trained staff, this is increasingly being challenged. There is a trend by some authors towards suggestions of more regionalised critical care services, as one potential solution.[23] A review by Singh and Mcdonald[24] explains that regionalisation entails the allocation of scarce healthcare resources on the basis of geography. Delivery of critical care would consist of a tiered system where a designated number of high-volume specialty referral centres would accept patients who require services not available locally, or who require a higher level of care than is provided at their local institution.[24] This type of "Hub and Spoke" model is not a novel one – and is clinically in place with referral-based systems being used for the more specialised fields such as cardiothoracic surgery and neurosciences, for whom it is generally accepted practice to have their own dedicated critical care units at various tertiary institutions. While the concentration of specialist services at major hubs is inevitable, local hospital care within geographically accessible areas for patients is essential.[23]

Whether all local or regional sites treating a certain acuity of patient or offering a surgical service should function with an on-site CCU is uncertain, and the sustainability of such a unit at these facilities remains debateable. An editorial by Suntharalingam G *et al*[23] published in 2014 focuses on this, and emphasizes the fact that all patients with critical illness, either at admission or arising during a hospital stay, have a right to early recognition of their condition, rapid access to critical care skills and decision-making, and timely access to facilities if deemed an appropriate candidate. Thus, it is crucial that the potential impact and public acceptability of a model supporting regionalised care be thoroughly researched and closely examined before implementation.

Some of the concerns and pitfalls of such a service include the distance of transfer and attendant delays in access; the potential clinical risks and hazards inherent in inter-site transfer of critically ill[25 ,26]; and strain on patients' families and carers if referred from far. Less experienced, potentially inappropriately trained care providers at referral medical or surgical units may also result in reduced speed of diagnosis and inadequate initial critical care treatment, warns Ward in a letter to the editor of *Anaesthesia* in 2015.[27]

Importantly, for such a model to have a chance at succeeding, adequate capacity must be planned for and provided at the destination hospitals and seamless referral and transfer pathways must be established, with safe and effective handover procedures. Some may be simple such as the familiar collaboration between anaesthetists and critical care. However, potentially hazardous situations should be avoided where junior anaesthetists are expected to cope with critically ill patients in 'temporary CCUs' (such as operating theatres, emergency departments) at referral hospitals that are not appropriately equipped or staffed to adequately manage such patients.[27] These 'temporary CCU's' also have an impact on service delivery, as they impede the use of that facility e.g. an operating theatre, until the patient is transferred to the tertiary institution.

Inter-hospital transfer is an independent risk factor for mortality in surgical patients requiring critical care.[25] However, when demand exceeds supply, or when a base hospital does not have an on-site CCU or facilities to provide the specialised care required, transfer of critically ill patients becomes necessary.

The goal during every inter-hospital transfer should be the continuation of high-quality critical care, while preventing deterioration or incidents. Although they may save lives if performed correctly, these transfers are expensive, logistically challenging, and potentially fraught with danger. It is increasingly accepted that specialised retrieval teams should transfer these patients. Unfortunately, these teams may frequently not be available. More research exploring inter-hospital transfers is necessary, but will prove challenging for several reasons including lack of definitions, or clarity on which outcomes should be assessed, and large variables in team and equipment composition.[28]

The transport process itself is associated with a risk of physiological deterioration and adverse events, proportional to the duration of the transfer, to the pre-transfer severity of illness or injury, and to the inexperience of the medical transport team.[26] Strikingly, a study by Flabouris *et al*[29] in 2006 reported that up to 91% of incidents were preventable. Factors associated with fewer incidents are good crew skills/teamwork, checking equipment and the patient, patient monitors and good interpersonal communication.

Even if transfers occur seamlessly, and all systems are perfectly in place, another important factor to consider is that although theoretical expense is spared on less critical care facilities at 'spoke' hospitals, the total cost of admitting a patient to a central hospital is probably significantly higher; both because the published average length of stay at a central hospital is 6,7 days versus 4,2 at regional, and with the cost per day more than double at a tertiary institution,[30] based on South African data by Ramjee in 2013. Although this would imply an increase in total admission costs for

patients deferred to a central hospital, there was no published data found that specifically evaluated the cost of patients transferred pre-operatively due to the potential need for critical care, making true comparison inaccurate at this stage.

Having a service that can provide and support surgery with an on-site critical care unit at a large district or regional hospital level could thus be considered as cost effective for the system. It is immensely difficult to measure the dual beneficial impact that such a service has – both on patients having quicker access to surgery and perioperative care regionally, and thus potentially decreasing the burden on referral centres, resulting in decreased delays and bed pressure there.

Primary regionalisation of adult general critical care is not straightforward and faces a number of challenges to be successful, and at this stage is only one of a number of potential reorganisation or optimisation strategies to be considered in critical care.

2.6 HDU's: An Alternative Postoperative Care Solution for Some

Patients often require an intermediate level of postoperative care during their hospital course. However, due to the significant difference between postoperative monitoring in CCU's and general wards, they are frequently admitted for postoperative monitoring. For this reason, the idea of HDU's has been introduced as a cost-effective way to improve access to an intensive care setting, without increasing the demand on the already stretched CCU bed supply. An HDU is broadly defined as an area where expertise and equipment to monitor and treat patients more aggressively than on a general ward are concentrated.[9] It should not contain patients requiring mechanical ventilation or with multiple organ failure, and typically has a nurse to patient ratio of 1:2 or 1:3.

In facilities where such a unit has been established, a decrease in inappropriate admissions to the CCU has been shown, as well as a reduction in cancellation of elective surgery[31] and a reduction in mortality by facilitating access to an intensive care environment.[32]

Without an HDU, literature shows that there is an approximate 25% CCU admission rate for HDU suitable patients, resulting in inappropriate use of resources. In contrast, patients meeting HDU criteria but sent to the ward, showed a large percentage of alteration in planned post-operative pain management and haemodynamic invasive monitoring plans respectively.[9] The absence of an intermediate care area facility thus impacts on the type of perioperative care provided to patients and the optimal use of resources.

3. Conclusion

Definitions regarding the divisions of critical care vary worldwide. Although access to and availability of critical care support also differ dramatically across the globe, it appears that the demand for beds is increasing everywhere. Due to a lack of adequately trained staff and the expense involved in sustaining a critical care unit, this demand is not simple to meet. Alternative options for improved perioperative care include the regionalisation of critical care services, and the provision of high care or high dependency units at smaller, regional hospitals.

After this literature search, it is evident that critical care support is required at regional level hospitals offering surgical services, but the research to support this is scarce. There is a pressing need to explore the benefits of on-site critical care facilities, including the utility and feasibility of HDU's. For improvements to be made regarding surgical outcomes, the provision of adequate postoperative care pathways and solutions must be found for the increasing demand for critical care beds. Current systems need to be assessed thoroughly in terms of outcomes, and the support they offer surgical services at their respective facilities.

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CHAPTER 2: Manuscript for publication in the *South African Medical Journal*

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service. Further research is required in this field to determine whether these results can be generalised to other regional hospitals. This survey should help as baseline data, especially for studies to better assess quality and outcomes against national and international metrics.

INTRODUCTION

In developing countries, resource limitations are inevitable. Staffing and equipping a costly critical care facility[1] and the role of critical care units may be considered to be unnecessary, especially in smaller institutions.[2] In the Western Cape, two new, large metro level-1 hospitals have been built without any critical care facilities. Concurrently in the United Kingdom (UK) there is consideration being given to consolidating critical care through the development of a 'hub-and-spoke' or regionalised critical care model with centralised, full-time critical care specialist-staffed units to provide a more effective and efficient use of critical care resources.[3]

The literature suggests that approximately 48% of critical care admissions are for postoperative patients.[4] A small survey was published in 2007 regarding general medical admissions to a South African regional hospital CCU,[5] and large multicentre studies focused on surgical outcomes in South Africa in 2017,[6] and Africa in 2018[7], respectively. However, there is no published South African or international data specifically describing the benefit of utilised or unutilised postoperative critical care support for surgery at regional hospital level. Bhat *et al*[8] evaluated postoperative critical care admissions in 2006 in Mumbai, India, but does not provide details on the percentage of cases done at the facility due to the option of on-site postoperative critical care.

A critical care bed is not essential for every surgical patient of a certain acuity, but just the availability of an on-site postoperative critical care option may allow a facility to proceed in offering higher risk patients surgery. This study aimed to quantify the surgical opportunities that such a critical care facility enables, at a regional level hospital in Cape Town.

The goals were to:

- Explore the incidence of patients who require the potential support of critical care at New Somerset Hospital (NSH)
- Identify which cases would not have been done at NSH if the option for postoperative critical care did not exist, and thus would have required preoperative referral (to a larger tertiary hospital) with the risk of delaying or decreasing access to a surgical opportunity, as well as utilising a potentially costlier resource
- Quantify the total percentage of patients requiring critical care postoperatively from the current theatre service offered at NSH
- Describe the indications for their admission to a critical care unit
- Assess the patient profiles requiring a higher level of postoperative care
- Describe the critical care requirements of patients admitted to the critical care service, and their postoperative care pathway

HYPOTHESIS: An on-site critical-care facility facilitates access to surgical services, in a hospital with a specialist anaesthesiologist led, fully functioning theatre complex. The potential for perioperative critical care also increases the acuity of cases that can be offered surgery, despite a portion of them not requiring critical care in the actual perioperative period.

METHODS

This was a prospective descriptive survey aimed at describing the role of critical care in supporting a regional hospital's surgical service, as well as profiling the patients receiving surgery at this hospital that require critical care admission, their clinical pathways and final outcomes.

The New Somerset Hospital in Cape Town, is a busy regional[9] (level 2) hospital with a substantial drainage area, funded by the Western Cape Government: Health, in South Africa (SA). It has 330 inpatient beds and a specialist led four-theatre complex consisting of three main theatres and an obstetric theatre. There are two anaesthetic consultants and four medical officers or registrars (trainee doctors) during normal working hours. The obstetric theatre, along with one emergency theatre is available after hours, with one non-specialist anaesthetist responsible for both. Surgical disciplines providing services include General Surgery, Gynaecology, Otolaryngology, Urology, and Orthopaedic and Obstetric surgery. There are also paediatric, internal medicine, psychiatry, radiology and emergency medicine departments.

A four-bed High Care Unit (HCU) provides a critical care service for patients requiring short term respiratory or cardiovascular support, or a higher level of monitoring than is possible in the general ward. Renal dialysis is not offered. One bed is dedicated for surgical patients, and three for medical admissions but two surgical patients may be admitted simultaneously for short periods. It is an 'open' critical care unit, with no dedicated doctor attending to intensive care in the unit at all times, and the admitting physician or surgical team being responsible for all the care and decisions regarding the patient's management while admitted. There is a trained intensive care nurse available per two patients (ratio of 1:2), with a staff nurse in the unit during the day as well.

The study included all surgical cases, elective and emergency, performed in the main and obstetric theatres at NSH from June to November 2015. Theatre cases using only local anaesthesia or conscious sedation, not assisted by an anaesthetist, were excluded. There were no other excluding criteria. Readmissions to the HCU from theatre (e.g. patients requiring relook exploratory laparotomies during their admission to the HCU) were included as part of the total number of cases performed in theatre, but not analysed as new admissions to the HCU.

Approval from the Ethics committee was gained prior to collection of data. (see Appendix A)

Two sets of data were collected, each on a separate data sheet:

1. On a simple tick sheet, data was collected from every case done in theatre – where, at the beginning of the case, the anaesthesia provider recorded the type of procedure, the emergency or elective nature of the case, whether admission to a CCU was planned, and whether it would have been done at NSH without the presence of CCU support on-site, given what was known at the start of the anaesthetic. At the end of the case, it indicated whether the patient was admitted to a CCU (at NSH or elsewhere) or not. (see Appendix B)

2. More detailed data was collected from every CCU admission directly from theatre: to the NSH HCU or any other CCU. This was obtained via a file survey with initial data entered as they were admitted, that was completed upon discharge from the CCU, or their death. For these patients, their demographic and comorbidity details including gender, age, ASA physical status and comorbidities (using the Charlson Deyo comorbidity index) were included, as well as details about their procedure, their postoperative critical care pathway and outcomes, interventions in the CCU, and related timelines. (see Appendix C)

'Critical care support' was defined as a patient either having a CCU bed booked preoperatively for admission after surgery or being admitted unexpectedly, or neither of these but the responsible anaesthetist indicated that the case would not have proceeded at NSH without the availability of an on-site CCU.

Patient confidentiality was maintained at all times. Prior to analysis, the data was collated by a single user, using a protected electronic database in the form of spreadsheets, and hard copies were immediately destroyed once captured.

RESULTS

3644 patients were documented from theatre records to have had surgery during the study period of six months. The study data set was captured from 3247 (89%) of cases, and these were all included in the analysis.

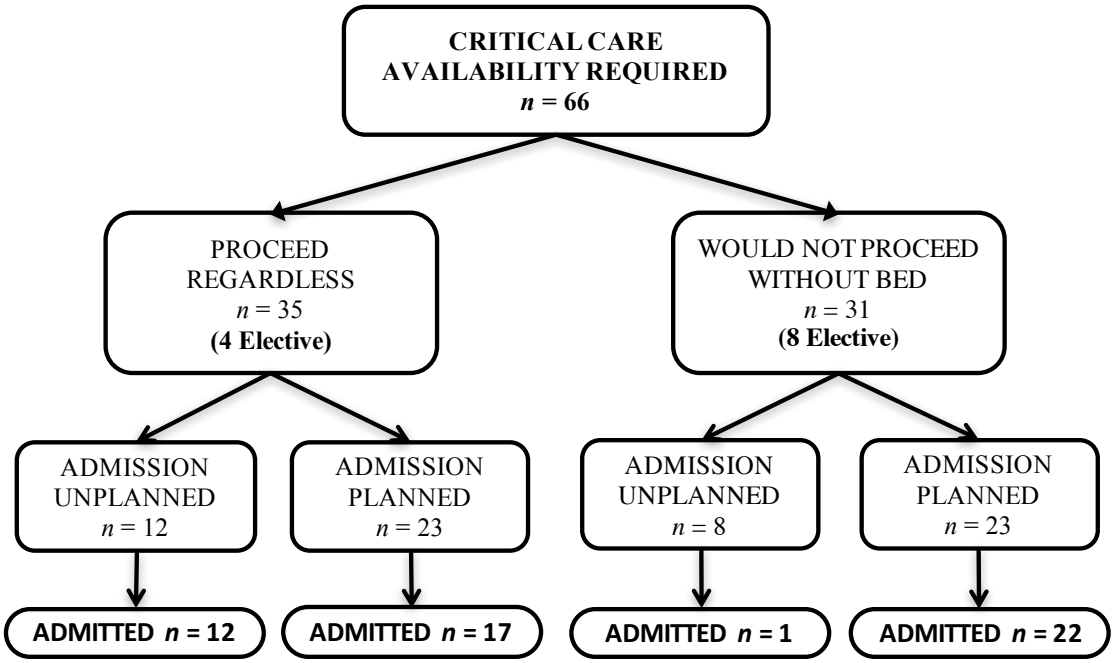

Figure 2. Flowchart of patients supported by critical care based on bed availability

In total, 66 (2%) patients required critical care support peri-operatively, of which 52 (78.8%) were admitted, including 3 re-admissions and 1 deceased patient whose file was lost. 31 (1%) cases would not have proceeded at NSH without the availability of an on-site critical care option. 7 (0.25%) cases would not have proceeded without the

possibility of a CCU bed, but did not actually have one booked, nor were they admitted. 18% of patients requiring support was for elective surgery.

	ADMITTED		NOT ADMITTED		Total
	n = 52* (%)		*n* = 14 (%)		
	PLANNED	UNPLANNED	PLANNED	UNPLANNED	*n* = 66 (%)
AGE					
<18	2 (3)	1 (1.5)	0 (0)	1 (1.5)	4 (6.1)
20-40	11 (16.7)	10 (15)	0 (0)	3 (4.5)	24 (36.4)
40-60	13 (19.7)	1 (1.5)	4 (6)	2 (3)	20 (30.3)
>60	8 (12)	6 (9)	3 (4.5)	1 (1.5)	18 (27.2)
DISCIPLINE					
Surgery	34*(51.5)	7 (10.6)	6 (9)	5 (7.5)	52 (78.8)
Orthopaedics	1 (1.5)	2 (3)	0 (0)	1 (1.5)	4 (6.1)
Obstetric	2 (3)	3 (4.5)	0 (0)	0 (0)	5 (7.6)
Gynaecological	0 (0)	1 (1.5)	1 (1.5)	0 (0)	2 (3)
Otolaryngology	2 (3)	0 (0)	0 (0)	0 (0)	2 (3)
Urology	0 (0)	0 (0)	0 (0)	1 (1.5)	1 (1.5)
OUTCOMES					
Death	8 (12)	4 (6)	1** (1.5)	0 (0)	13 (19.7)

* including 1 admission file lost and 3 re-admissions

**death on table

Table 6. Details of patients requiring critical care support

General surgical patients formed the bulk of all patients requiring support (78.8%). The majority of all patients were in the 20–40 year age group (36.4%), and 87.5% of this particular group were also admitted. There were 41 admissions planned overall, yet of these 34 were admitted. Of the 5 obstetric patients requiring support, 3 admissions were unplanned, yet all were eventually admitted postoperatively. The total mortality rate was 19.7%, and among all admissions (including re-admissions) was 18.1%. There was only one death among patients not admitted, and it occurred while still in theatre.

48 patients (1.5%) were new admissions to a critical care unit directly from theatre over the six months. The data of the 3 readmissions where patients went to theatre from the unit and returned postoperatively, and the deceased male whose file was lost, was excluded from further analysis.

The data related to patient profiles and their critical care pathway was divided into three groups, and each was analysed:

1. Preoperative variables
2. Intraoperative variables
3. CCU admission details

1. Preoperative variables/Demographics

a. Age and Gender

b. ASA (American Society of Anaesthetists) physical status

c. Comorbidities (Charlson Deyo Index)

	MALE	FEMALE	Total
	***n* = 24 (%)**	***n* = 24 (%)**	***n* = 48 (%)**
AGE			
<18	2 (4.2)	1 (2.1)	3 (6.3)
20-40	10 (20.8)	11 (22.9)	21 (43.7)
40-60	5 (10.5)	7 (14.5)	12 (25)
>60	7 (14.5)	5 (10.5)	12 (25)
ASA			
1	16 (33.3)	6 (12.5)	22 (45.8)
2	2 (4.2)	9 (18.7)	11 (22.9)
3	4 (8.3)	6 (12.5)	10 (20.8)
4	2 (4.2)	3 (6.3)	5 (10.5)
COMORBIDITIES**			
0	12 (25)	9 (18.7)	21 (43.7)
1-3	6 (12.5)	8 (16.7)	14 (29.2)
4-6	5 (10.5)	6 (12.5)	11 (22.9)
>6	1 (2.1)	1 (2.1)	2 (4.2)

* excluding 1 lost admission file

** according to Charlson Deyo classification

Table 7. Preoperative variables

An equal number of female and male patients was admitted, with a similar age distribution. The largest age group represented was the 20-40 year group. Patients with a low ASA and less comorbidities were noted to be the most common among admissions. Conversely, the least patient groups to be admitted were those with a high comorbidity or ASA rating.

2. Intraoperative Variables

a. Nature of Surgery – elective/emergency

b. Surgical Discipline

	EMERGENCY	ELECTIVE	Total
	***n* = 43 (%)**	***n* = 5 (%)**	***n* = 48* (%)**
SURGICAL DISCIPLINE			
Otolaryngology	1 (2.1)	1 (2.1)	2 (4.2)
General Surgery	33 (68.8)	4 (8.3)	37 (77.1)
Gynaecology	1 (2.1)	0 (0)	1 (2.1)
Obstetric	5 (10.4)	0 (0)	5 (10.4)
Orthopedic	3 (6.2)	0 (0)	3 (6.2)
Urology	0 (0)	0 (0)	0 (0)
Total	**43 (89.6)**	**5 (10.4)**	**48 (100)**
* excluding 1 lost admission file			

Table 8. Nature of Surgery and Surgical Discipline

The majority of patients requiring admission postoperatively were those receiving emergency procedures, with elective patients contributing only 10.4% to the total number of new admissions. Urology had none, and orthopaedic surgery only 6.2%. Obstetrics and gynaecology together represented 12.5% of admissions.

3. Admission Details

Regarding new admissions to the CCU, the mortality rate was 23%, with a similar distribution amongst males and females. Patients who survived were younger and had low ASA grades and APACHE II (Acute Physiological and Chronic Health Evaluation) scores (see Appendix E). Planned admissions had a mortality rate of 23%, and unplanned admissions a rate of 22%.

	ALIVE	DIED	Total
	n = 37 (%)	*n* = 11 (%)	*n* = 48 (%)
GENDER			
Male	19 (51.3)	5* (45.5)	24 (50)
Female	18 (48.7)	6 (54.5)	24 (50)
ASA			
1	20 (54.1)	2 (18.2)	22 (45.8)
2	11 (29.7)	0 (0)	11 (22.9)
3	6 (16.2)	4 (36.3)	10 (20.8)
4	0 (0)	5 (45.5)	5 (10.5)
AGE			
<20	3 (8.1)	0 (0)	3 (6.3)
20-40	19 (51.3)	2 (18.2)	21 (43.8)
40-60	8 (21.6)	4 (36.3)	12 (25)
60-80	4 (10.9)	4 (36.3)	8 (16.7)
>80	3 (8.1)	1 (9.2)	4 (8.2)
NATURE OF SURGERY			
Emergency	32 (86.5)	11 (100)	43 (89.5)
Elective	5 (13.5)	0	5 (10.5)
ADMISSION			
Planned	23 (62.2)	7 (63.7)	30 (62.5)
Unplanned	14 (27.8)	4 (36.3)	18 (37.5)
INTERVENTIONS			
Epidural care	3 (8.1)	0 (0)	3 (6.3)
Monitoring only	17 (45.8)	2 (18.2)	19 (39.6)
Ventilation only	16 (43.2)	2 (18.2)	18 (37.5)
Inotropes only	0 (0)	1 (9.2)	1 (2.9)
Ventilation and Inotropes	1 (2.9)	6 (54.4)	7 (13.7)
APACHE II**	***n* = 35 (%)**	***n* = 11 (%)**	***n* = 46 (%)**
<5	9 (25.7)	0 (0)	9 (19.6)
5 to 10	11 (31.4)	1 (9.1)	12 (26.1)
10 to 15	12 (34.3)	0 (0)	12 (26.1)
15 to 20	2 (5.7)	5 (45.5)	7 (15.2)
20 to 25	1 (2.9)	4 (36.3)	5 (10.4)
>25	0 (0)	1 (9.1)	1 (2.6)

*excluding 1 patient (file lost)
**excluding 1 patient under age 1 (APACHE not validated for children), and one maternity file lost in transfer to tertiary obstetric CCU

Table 9. Description of patients admitted to CCU

	n = 48 (%)
INTERVENTIONS	
Epidural care	3 (6.25)
Monitoring only	19 (39.5)
Ventilation only	18 (37.5)
Inotropes only	1 (2)
Ventilation and Inotropes	7 (14.75)

Table 10. Interventions received during CCU admission

55% of patients were admitted for cardiorespiratory support, while 45% required monitoring or epidural care only.

DISCUSSION

Principal Findings

Not all patients supported by critical care require admission. During this study period, 14 cases were identified preoperatively as possibly requiring support, yet were not actually admitted to a CCU postoperatively. 31 cases would not have proceeded at NSH without availability of an on-site critical care bed, and would have been transferred to a tertiary facility pre-emptively before receiving their surgery. An important cohort identified within this group, are the patients that received their surgery at NSH due to the availability of critical care support on-site, but were never admitted to a CCU. This subgroup of patients has to our knowledge not been measured before: those not admitted to a CCU, had no formal bed booked, but yet received surgery at their facility solely due to the potential of postoperative critical care support there.

1.5% of all cases performed were admitted to a CCU. It is interesting that the largest age group admitted was the 20-40 year category (43.7%). Patients with a physical ASA status of 1 also accounted for almost half of all admissions. This suggests that young previously healthy or low risk patients presenting for surgery have surprisingly high critical care support requirements. This finding is in keeping with two large multicentre studies published recently.[6 ,7]

Previously published work demonstrated that the majority of patients requiring admission postoperatively are for general surgical emergencies, and this was echoed in this survey. Although regional or Level-2 obstetric services are for healthy ASA 1 or 2 patients, they contributed 10.4% of the emergency admissions, indicating that otherwise low risk pregnant patients also require critical care support. 3 of these patients were unplanned admissions, thus required support for unexpected anaesthetic or surgical complications.

The precise indications for patients' postoperative admission to a critical care unit were not specifically documented, yet from interventions received in CCU, it is evident that only 55% of patients received cardiorespiratory support. 45% received monitoring or epidural care only, implying that perhaps for the current surgical services offered, a facility simply providing higher monitoring than in the general ward would be sufficient. High dependency units (HDU) are well described in

literature[2 ,10] and as they do not offer ventilatory support, they require fewer nurses per patient and are not as expensive to equip or staff.[1]

Although outcomes and quality of care of the New Somerset CCU were not directly measured, and the study was not powered to measure this, it was surprising that unplanned admissions during this study period did not seem to have a higher mortality rate as presented in several other publications.[11-13]

Strengths and weaknesses of the study
Designing a study to assess the need for critical care support is not simple. Many factors influence a patient's postoperative care pathway. Often it is simply the subjective opinion of the attending surgeon or anaesthetist that determines whether a patient requires a higher level of care or not. It is also resource dependent, even at the same facility. Determining the percentage of patients requiring critical care support postoperatively from NSH during the time period mentioned, was dependent on the responsible anaesthetist to make that decision as they completed the data sheet, which assumed that they had a shared understanding of the need.

The survey did not investigate the ages, ASA status or comorbidities of the total population studied, only those who were admitted to a CCU, so no comparison was possible between the two groups. The ASA is also a subjective measure of a patient's physiological status, and thus a potentially flawed tool.

Other limitations include the difficulty in comparing these findings with other institutions due to wide differences in defining the various critical care facilities, across the globe. [14] The 89% data sheet completion rate for all cases performed was acceptable, as there was no reason to believe that data was skewed towards measuring an increased rate of CCU admission.

Contribution to the body of knowledge
There is no published data previously related to opportunities allowed or created by the presence or availability of an on-site critical care facility at regional level. This survey provides baseline information, and highlights issues for further work.

Meaning of this study to clinicians and policymakers
There were 5 elective cases included in the overall group of new admissions, yet there were another 4 elective patients assessed as potentially requiring support, who were not admitted postoperatively but where surgery proceeded due to the critical care availability at NSH. They form part of the cohort of patients that benefited from increased access to surgical opportunity and avoided the risk of delaying their surgery. It is immensely difficult to measure the dual beneficial impact that this has – on patients having their surgery sooner and the option of perioperative care regionally should they have needed it, and thus also potentially decreasing the burden on referral centres, resulting in decreased delays and bed pressure there.

Unanswered questions and recommendations for future research
This was not a study designed to look at critical care quality and outcomes, but to assess the benefits to a surgical service of the CCU resource. Further studies need to explore the detailed outcomes from surgical patients who benefit from CCU support

at regional hospital level. The number of critical care beds required for a particular surgical service should be measured, as well as the feasibility of regional HDU's.

CONCLUSION

This research confirms that at NSH, the peri-operative support and availability of an on-site CCU allows for cases to proceed that would otherwise have been transferred elsewhere, whilst also collating the data from the total number of patients who receive the benefit of access to surgical opportunity here. Further research is required in this field to determine whether the results can be generalised to other regional hospitals. This survey aims to assist with future studies by providing baseline data, especially for those planning to better assess quality and outcomes against national and international metrics. This assessment and analysis of the requirements for critical care within an organised health service in South Africa, should be of potential benefit not only to health system planners and managers, but also to clinicians responsible for providing and governing the associated clinical services.

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APPENDICES

Appendix A: Approval letter from Ethics Committee

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
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01 July 2015

HREC REF: 402/2015

Dr AR Reed
Anaesthesia
D23
NGSH

Dear Dr Reed

PROJECT TITLE: ASSESSING THE SUPPORT ROLE FOR SURGERY, PROVIDED BY A HIGH CARE UNIT, IN A REGIONAL HOSPITAL: A PROSPECTIVE AUDIT OF PLANNED AND UNPLANNED POSTOPERATIVE HIGH-CARE ADMISSIONS AT NEW SOMERSET HOSPITAL (FCA-MMed-candidate-Dr K Delport)

Thank you for your response to the Faculty of Health Sciences Human Research Ethics Committee dated 29 June 2015.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th July 2016.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that Dr Kathleen Delport will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH

Appendix B: Data sheet for all cases

PLANNED AND UNPLANNED ADMISSIONS TO NSH HIGH CARE: an audit of all theatre cases

Date: Filled in by: List/Discipline:

Patient name/sticker and ASA status	Procedure	Nature of Surgery		Postop Highcare Planned?		Proceed with case if no Highcare?		Went to Highcare?	
		Emergency	Elective	YES	NO	YES	NO	YES	NO

Appendix C: Data sheet for all new admissions

AUDIT OF POSTOPERATIVE HCU ADMISSIONS - NEW SOMERSET HOSPITAL

1. Hospital Nr (or sticker)		**2. Sex**	□ Male □ Female
3. Date of: **3.1 Hospital admission**		**3.2 Hospital discharge/death**	
3.3 HCU admission		**3.4 HCU discharge/death**	
4. Age		**5. ASA physical status**	
6. Comorbidities (Deyo/Charlson Index)		**7. Surgical diagnosis and planned procedure**	
8. Discipline involved	□ General Surgery □ Orthopaedics □ ENT □ Gynae/Obstetrics	**9. Nature of surgery***	□ Immediate □ Urgent □ Expedited □ Elective
10. Anaesthetic technique	□ General anaesthesia □ Regional anaesthesia	**11. Duration of anaesthesia (min)****	
12. Type of HCU admission	□ Planned □ Unplanned	**13. Immediate postoperative transfer to other HCU/ICU - *and why***	□ No □ Yes: Hospital_____
14. <u>In case of emergency</u>: **14.1 Time from admission at primary facility to NSH arrival (hours)**		**14.2 Time from arrival in Hospital to theatre (hours)**	
15. Intervention in HCU	□ Monitoring only □ Mechanical Ventilation □ Inotropic support □ Epidural Care	**16. Case managed by**	□ Surgeon □ Physician □ Anaesthetist □ Other
17. Days in HCU***		**18. Days ventilated********	
19. APACHE II score (taken on ICU admission)		**20. Patient seen by visiting GSH intensivists**	□ Yes □ No
21. Outcome **Short term (From HCU to....)**	□ Ward □ Other ICU □ Death	*Data Collected by:*	*Date:*

***NCEPOD Classification of Intervention (UK)**

IMMEDIATE – Immediate life, limb or organ-saving intervention – resuscitation simultaneous with intervention. Normally within minutes of decision to operate.

URGENT – Intervention for acute onset or clinical deterioration of potentially life- or limb-threatening conditions. Normally within hours of decision to operate.

EXPEDITED – Patient requiring early treatment where the condition is not an immediate threat to life, limb or organ survival. Normally within days of decision to operate.

ELECTIVE – Intervention planned or booked in advance of routine admission to hospital. Timing to suit patient, hospital and staff.

**** Start of anaesthesia is when monitors are applied**
***** Day of admission is day 1 (day 2 starts at midnight)**
****** Start of ventilation is day 1 (day 2 starts at midnight of that day)**

Appendix D: Charlson Deyo Comorbidity Index

Table 1. Charlson Comorbidity Index Scoring System

Score	Condition
1	Myocardial infarction (history, not ECG changes only)
	Congestive heart failure
	Peripheral vascular disease (includes aortic aneurysm ≥6 cm)
	Cerebrovascular disease: CVA with mild or no residua or TIA
	Dementia
	Chronic pulmonary disease
	Connective tissue disease
	Peptic ulcer disease
	Mild liver disease (without portal hypertension, includes chronic hepatitis)
	Diabetes without end-organ damage (excludes diet-controlled alone)
2	Hemiplegia
	Moderate or severe renal disease
	Diabetes with end-organ damage (retinopathy, neuropathy, nephropathy, or brittle diabetes)
	Tumor without metastases (exclude if >5 y from diagnosis)
	Leukemia (acute or chronic)
	Lymphoma
3	Moderate or severe liver disease
6	Metastatic solid tumor
	AIDS (not just HIV positive)

NOTE. For each decade > 40 years of age, a score of 1 is added to the above score.

Abbreviations: ECG, electrocardiogram; CVA, cerebrovascular accident; TIA, transient ischemic attack; AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.

The APACHE II Score

Physiologic Variable	High Abnormal Range					Low Abnormal Range			
	+4	+3	+2	+1	0	+1	+2	+3	+4
Rectal Temp (°C)	≥41	39-40.9		38.5-38.9	36-38.4	34-35.9	32-33.9	30-31.9	≤29.9
Mean Arterial Pressure (mmHg)	≥160	130-159	110-129		70-109		50-69		≤49
Heart Rate	≥100	140-179	110-139		70-109		50-69	40-54	≤39
Respiratory Rate	≥50	35-49		25-34	12-24	10-11	6-9		≤5
Oxygenation a) FIO_2≥0.5 record A-aDO_2 b) FIO_2<0.5 record PaO_2	≥500	350-499	200-349		<200 PO_2>70	PO_2 61-70		PO_2 55-60	PO_2<55
Arterial pH	≥7.7	7.6-7.69		7.5-7.59	7.33-7.49		7.25-7.32	7.15-7.24	<7.15
HCO_3 (mEq/l)	≥52	41-51.9		32-40.9	22-31.9		18-21.9	15-17.9	<15
K (mEq/l)	≥7	6-6.9		5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		<2.5
Na (mEq/l)	≥100	160-179	155-159	150-154	130-149		120-129	111-119	≤110
S. Creat (mqm/dl)	≥3.5	2-3.4	1.5-1.9		0.6-1.4		<0.6		
Hematocrit (%)	≥60		50-59.9	46-49.9	30.45.9		20-29.9		<20
TLC (10^3/cc)	≥40		20-39.9	15-19.9	3-14.9		1-2.9		<1
GCS									

Age -score

<44 → 0
45-54 → 2
55-64 → 3
65-74 → 5
≥75 → 6

GCS:

15 → 0
14 → 1
13 → 2
12 → 3
11 → 4
10 → 5
9 → 6
8 → 7
7 → 8
6 → 9
5 → 10
4 → 11
3 → 12

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Appendix F: Author's Guidelines for *South African Medical Journal*

General:

- Manuscripts must be written in UK English.
- The manuscript must be in Microsoft Word or RTF document format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).
- Please make your article concise, even if it is below the word limit.
- Qualifications, ***full*** affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.
- Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
- Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).
- Litres is denoted with an uppercase L e.g. 'mL' for millilitres).
- Units should be preceded by a space (except for % and ºC), e.g. '40 kg' and '20 cm' but '50%' and '19ºC'.
- Please be sure to insert proper symbols e.g. µ not u for micro, a not a for alpha, b not B for beta, etc.
- Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.
- Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
- Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.
- If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the *only* exception. Please DO NOT use fill, format lines and so on.

Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text .

Structured abstract

- This should be 250-400 words, with the following recommended headings:
  - **Background:** why the study is being done and how it relates to other published work.
  - **Objectives:** what the study intends to find out
  - **Methods:** must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.
  - **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
  - **Conclusion:** must be supported by the data, include recommendations for further study/actions.
- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts.

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc)that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results

- Start with description of the population and sample. Include key characteristics of comparison groups.
- Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- Do not replicate data in tables and in text.
- If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:
- E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the ± symbol for mean (SD).
- Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

- Statement of principal findings
- Strengths and weaknesses of the study
- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
- The meaning of the study – e.g. what this study means to clinicians and policymakers
- Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.